UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS – EASTERN DIVISION

MARY CRUMPTON, individually and on behalf of all others similarly situated, Plaintiff, v. OCTAPHARMA PLASMA, INC., Defendant.	)	Case No. 1:19-cv-08402 Judge Virginia M. Kendall

DECLARATION OF MONICA H. BYRD IN SUPPORT OF OCTAPHARMA PLASMA, INC.'S OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE ITS FIRST AND SECOND AFFIRMATIVE DEFENSES

I, Monica H. Byrd, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I have personal knowledge of the matters set forth in this declaration and would be competent to testify thereto at trial or at a hearing on this matter.

2. I am currently employed as Senior Director of Regulatory Affairs and Quality Assurance by Octapharma Plasma Inc. ("Octapharma"). I have served in this capacity since 2013. I work in Octapharma's headquarters located in Charlotte, North Carolina.

3. I am familiar with Octapharma's policies and procedures relating to Octapharma's collection, testing and manufacture of Source Plasma from its donors in a manner that satisfies applicable federal and state laws and regulations enacted to ensure that the supply of Source Plasma is safe and to provide life-saving treatments and therapies for patients in health care settings around the world.

4. Source Plasma is the fluid portion of human blood, comprising water, salts, enzymes, antibodies and other proteins, collected through plasmapheresis from healthy voluntary human donors.

5. In order to ensure that the supply of Source Plasma is safe to fulfill its critical purpose, in collecting, testing and manufacturing Source Plasma for efficacy, Octapharma must meet the specific standards and requirements set forth in regulations implemented by the U.S. Food and Drug Administration ("FDA") at each of its facilities, including the nine (9) that Octapharma now operates in the State of Illinois.

6. Since each Octapharma facility operates a clinical laboratory that tests the blood and Source Plasma it collects from donors, Octapharma is subject to the federal Clinical Laboratory Improvement Amendments Act of 1988 ("CLIA"). As Octapharma's Illinois facilities are certified under CLIA as clinical laboratories, Octapharma must and does maintain a license under the Illinois Clinical Laboratory and Blood Bank Act (the "Illinois Laboratory Act").

7. Octapharma also is subject to the industry standards and programs administered by the Plasma Protein Therapeutics Association ("PPTA"). These globally-applied standards and programs ensure the quality and safety of Source Plasma collection and manufacturing processes to protect both donors and patients around the world. Among its initiatives, PPTA launched the Cross Donation Check System database, developed and operated by Haemonetics, that assists plasma donation centers throughout the United States by enabling participating plasma collection facilities to search other facilities' records in a unified repository to prevent impermissible donor cross-donations at different plasma collection centers, and the National Donor Deferral Registry ("NDDR") database of permanently deferred (prohibited) source plasma donors in North America due to "reactive" test results for HIV, HBV, and HCV that is administered by Haemonetics.

8. Octapharma complies with the PPTA protocols because they ensure compliance with applicable FDA regulations associated with positively identifying and screening each donor and their plasma donations.

Octapharma complies with the FD&C Act and FDA regulations

9. Octapharma holds an FDA Biologics License (License No. 1817 currently in good standing) for its collection of Source Plasma. Octapharma's collection and storage methods allow it to "demonstrate that [its] manufactured product m[et] prescribed requirements of safety, purity, and potency" as required by 21 C.F.R. § 601.20, attached as Exhibit 1.

10. For its clinical testing of the Source Plasma and blood obtained from its donors in accordance with scientifically proven methodologies, Octapharma is certified and licensed under CLIA and its Illinois facilities are licensed pursuant to the Illinois Laboratory Act. Octapharma's CLIA and Illinois Laboratory Act licenses are in good standing, attached as Exhibit 2.

11. In order to obtain and maintain all the information related to its donors, to develop policy requirements and workflows that satisfy FDA regulatory requirements for determining donor suitability, to track the donated and manufactured Source Plasma, and to comply with the recordkeeping requirements imposed by applicable law and regulations, Octapharma implemented a donor management system using Haemonetics' software and devices. Such devices are regulated by the FDA as a medical device, as it is specialized to the requirements imposed on plasma donation facilities and facilitating FDA compliance.

12. From April 2009 through August, 2019, Octapharma used the Haemonetics eQue™ Donor Management System software. Thereafter, Octapharma operates Haemonetics' NexLynk™ Donor Management System software (collectively, the "DMS").

13. In accordance with applicable law and regulations, including 21 C.F.R.§ 600.100, Octapharma has implemented policy requirements and procedures for determining the eligibility of a donor for a suitable plasma donation by evidencing that the donor is in good health and free from "relevant transfusion-transmitted infections." Octapharma's Donor Suitability and Processing Policy, as well as the supporting Screening Evaluation and Physical Examination procedure documents are collectively, the "Suitability Policy".

14. The instructions and procedures detailed in the Suitability Policy must be followed and completed with medically acceptable results before a donor is allowed to donate plasma at Octapharma. The procedures include performing an in-depth health screening during the donor's initial visit; conducting and reviewing the donor's answers to an in-depth medical questionnaire; determining the donor is not deferred from donating plasma; performing a physical assessment of the donor's health vitals and characteristics, including temperature, blood pressure, hemoglobin or hematocrit level, pulse and skin condition; evaluating all body modifications, tattoos, piercings and non-surgical scars; performing an initial and annual head-to-toe physical examination; presenting and discussing educational materials; administering red blood cells to the donor (where applicable); obtaining written informed consents from the donor; taking blood and plasma samples for testing; as well as performing laboratory tests on those blood and plasma samples and medically evaluating the testing results.

15. Octapharma's Suitability Policy requires having a licensed medical doctor (the "Medical Director") and a physician substitute at every site where Octapharma collects Source Plasma to physically assess donors and review donor records.

16. In accordance with its Suitability Policy, when a prospective donor enters an Octapharma donation facility, the donor is asked to provide a current and valid photo identification

card (such as a driver's license), proof of Social Security number and proof of a current mailing address where the donor expects he can be contacted after donation.

17. The donor is checked-in and directed to an available kiosk for their identification, screening and authorizations. The kiosk comprises an electronic hardware device containing a touch screen user interface and an attached finger scanning device (collectively, the "Kiosk"). The Kiosks operate using the DMS.

18. Pursuant to federal regulations, Octapharma was required to and established a system that positively identifies each donor and that the positive identification information maintained in its system relates to each donor directly, to each step a donor undertakes to evidence their eligibility to donate suitable Source Plasma, to each instance that Source Plasma was obtained from that donor, as well as to that donor's accumulated records and laboratory data.

19. Visual identification from a photograph can result in false identification, for example in the instance of identical twins. Therefore, Octapharma utilizes the information derived from a finger scan (from which the DMS creates a template for the donor) to ensure the positive identification of its donors.

20. At the Kiosk, under supervision by an Octapharma employee at their initial visit, the donor is directed to insert their finger into the finger scanning device and input their birth date using the touchscreen of the Kiosk.

21. The donor's insertion of their finger into the scanning device causes the scanning device to identify distinguishing characteristics of the inserted finger without maintaining any image or record from the underlying finger scan and to generate a digital or binary code based on those characteristics comprising letters, numbers and special characters (the "Template"), which the DMS then compares against the Template information maintained in Octapharma's DMS for

that donor (collectively, these processes are Octapharma's Positive Donor Identification system in accordance with 21 C.F.R. § 640.65(b)(iv)(3)).

22. Each donor's Template and related information are maintained by the DMS within that donor's Donor History Record.

23. After Positive Donor Identification, a first-time donor, or any donor who has not donated plasma within the past six (6) months, to Octapharma is presented with a series of health history related questions for input of self-administered required responses at the Kiosk (the "Health History Questions").

24. The phrasing of the Health History Questions utilized by Octapharma have changed over time, but generally relate to the following:

a. The donor's possible exposure or a positive test result for HIV or AIDS;

b. The donor's use of needles to take drugs, steroids, or anything not prescribed by their doctor;

c. The donor's sexual behavior, including frequency, partners who have same-sex sexual activity or use drugs, and prostitution;

d. The donor's gender at birth;

e. The donor's medical care by a doctor for any health problem;

f. The donor' known medical conditions or diseases;

g. The donor's diagnosis of Creutzfeldt-Jakob Disease (CJD);

h. The donor's affirmation that all questions about their health were answered honestly; and

i. The donor's request for a chaperone (another employee in the room) during the physical exam.

25. Thereafter, the first-time and any returning donor who donated plasma to Octapharma within the past six (6) months is presented with a series of additional health history related questions and Creutzfeldt-Jakob Disease (CJD) travel-related questions for input of self-administered required responses at the Kiosk (respectively, the "Pre-Donation Health Questions" and "CDJ Travel Questions").

26. The phrasing of the Pre-Donation Health Questions has also changed over time, but include questions generally relating to the following:

a. The donor's confirmation that donor has read and has no questions about the information posters that all donors must review, relating to plasmapheresis, risks and medications;

b. The donor's general perception of their health;

c. The donor's disclosure of events, such as emergency room or urgent care visits, hospital stays, surgery, endoscopic or surgical procedures, as well as dental work during a specified period of time prior;

d. The donor's disclosure of new health issues, medications or treatments during a specified period of time prior;

e. The donor's recent use of antibiotic or other treatment for an infection;

f. The donor's recent health symptoms;

g. The donor's body modification or other procedures that break the skin, including tattoos, permanent make-up, piercings, intentional scars, and acupuncture during a specified period of time prior;

h. The donor's incarceration for any consecutive period longer than 72 hours;

i. The donor's donation of plasma or platelets during the prior 7 days or blood during the past 4 months;

j. The donor's immunizations or exposure to smallpox vaccine during a specified period prior;

k. The donor's disclosure of her pregnancy or related events;

l. The donor's possible exposure to hepatitis or other diseases, such as Ebola;

m. The donor's exposure to or positive test result for HIV/AIDS; and

n. The donor's confirmation that photo identification and postal address were previously provided, that the plasma donation is not being used to get an HIV/AIDS diagnosis, and that all questions were answered honestly;

o. The donor's acknowledgement that all informational materials relating to infections the donor's plasma could transmit to others were reviewed, that the donor agrees not to donate if the donation could be a risk to others, that the donor understands their donation will be tested for infections, that the donor understands that attempts at contact will be made if the donation cannot be used that deferral's records will be maintained, that the donor has reviewed information relating to the risks associated with donating plasma, and that the donor has been given an opportunity to ask questions and that the donor can withdraw at any time.

27. The CDJ Travel Questions relate to whether the donor travelled to countries where exposure to Creutzfeldt-Jakob Disease was possible.

28. A donor's affirmative response to any of the Health History Questions, Pre-Donation Health Questions, and CDJ Travel Questions, can result in an additional series of

questions to the donor at the Kiosk to solicit additional facts and circumstances pertaining to the affirmative answer.

29. All of the donor's inputted responses to the Health History Questions, Pre-Donation Health Questions, and CDJ Travel Questions, and any additional questions are maintained by the DMS within that donor's Donor History Record, linked to that donor's Template for positive donor identification.

30. Additionally, pursuant to its Suitability Policy, Octapharma determines whether the donor has not been permanently deferred (determined to be ineligible) from donating Source Plasma through the NDDR and its records. Octapharma's DMS interfaces with the NDDR to add the name of any of its donors permanently deferred from donating Source Plasma.

31. Upon completion of the Health History Questions, Pre-Donation History Questions, and CDJ Travel Questions, the donor is moved from the Kiosk to a booth for screening and physical assessment.

32. If that donor is new to Octapharma or has not donated within the past six (6) months, in accordance with its Suitability Policy, the donor is provided with a New Donor Binder containing introductory and educational documents relating to the plasma donation procedure and its risks, as well as the risks posed by certain donor behaviors and infections that are transmissible to a plasma recipient.

33. The donor is moved to a private screening area or booth where a Medical Screener first obtains positive identification of the donor in the DMS, which is easily verified by the donor's finger scan.

34. In accordance with its Suitability Policy, Octapharma's Medical Screener also verifies donor's photo identification and Social Security documentation against the information

previously inputted, and then confirms that the donor has not exceeded the two allowable Source Plasma donations within any seven-day period.

35. Octapharma's DMS directly interfaces with another software system developed by Haemonetics, the Cross-Donation Check System ("CDCS") to access the records of all participating plasma donation centers.

36. So that the CDCS maintains accurate information, Octapharma (and all participating plasma donation centers) input identifying information about the donor and date of donation into the CDCS at the time of donation. Thus, during the screening process, the information inputted into Octapharma's DMS queries the CDCS system and results in a search result showing the last donation date from that donor's history to ensure that the donation limit is not exceeded.

37. Following detailed procedures based on specific result criteria, the Medical Screener then performs a screening evaluation of the donor's vitals, including weight, physical appearance, arm and venipuncture location condition, hematocrit fingerstick test, temperature, blood pressure, pulse, and total protein test. Throughout, the Medical Screener contemporaneous inputs the results into the DMS, which maintains the results tied to that donor's records.

38. If any result from the screening procedures is unacceptable or reflects a technical error, the Medical Screener performs a retake of those vitals, addresses technical errors, refers consistently out-of-limit results to the Medical Director or physician substitute and documents each action and result within the DMS.

39. To the extent the results from the Medical Screener relating to the donor's physical appearance, arm and venipuncture location condition, temperature, blood pressure or pulse are unacceptable, Octapharma's physician substitute performs further evaluation, counsels the donor

for vital results that are repeatedly out-of-limit and defers the donor from donating Source Plasma for the amount of time designated in the Suitability Policy where appropriate.

40. Octapharma provides medical supervision for each site where Source Plasma is collected through each site Medical Director, and through the physician substitute(s) Octapharma employs to be on-site at each facility.

41. Octapharma allows that certain medical determinations may be delegated to its on-site physician substitute in consultation with the Medical Director.

42. Upon completion of the screening, a new donor and a returning donor is moved to an examination room for a physical examination by Octapharma's Medical Director or physician substitute, where Positive Donor Identification is first obtained by finger scan.

43. After reviewing the donor's earlier inputted responses at the Kiosk and addressing any responses flagged by the DMS as requiring further assessment, the Medical Director or physician substitute determines whether the presence of a chaperone or third-party inspector during the physical examination is acceptable to the donor, documents information about the chaperone or inspector if applicable, and obtains informed consent from the donor by electronic signature on an electronic signature pad connected to Octapharma's DMS.

44. The Medical Director or physician substitute then questions the donor about all prescription and over-the-counter medications taken during the past sixty (60) days and the reasons for taking the medication in order to make a medical determination whether to approve each medication or to defer the donor from donating Source Plasma. The information for each medication, the donor's reason for taking the medication and the approval or deferral is documented in the DMS and maintained with that donor's Donor History Record.

45. If applicable, the Medical Director or physician substitute then performs an evaluation of the donor's body art, such as tattoos and piercings, by interviewing the donor, mapping their location(s) on an interactive body map within a DMS device, and obtaining consent to the body art information by the donor through electronic signature on the electronic signature pad device connected to the DMS, which consent is maintained in that donor's Donor History Record.

46. Next, the Medical Director or physician substitute is required to acknowledge in the DMS that the donor's prior responses to the Health History Questions and Pre-Donation Health Questions are acceptable, that the medications previously documented are acceptable, and that any questions that the donor may have based on the educational information previously provided to the donor regarding plasmapheresis risks and risks to plasma recipients have been answered.

47. The Medical Director or physician substitute then performs a head to toe physical examination of the donor without requiring the donor to fully disrobe.

48. The components of the physical examination include the following:

a. assessment of the donor's general appearance, neurological, musculoskeletal, and psychiatric health;

b. assessment of the donor's head, eyes, mouth, nose, throat, neck and lymph nodes;

c. assessment of the donor's heart, chest and lungs;

d. assessment of the donor's abdomen; and

e. assessment of the donor's extremities.

49. All findings and results from the physical examination are to be documented as acceptable or not acceptable by the Medical Director of physician substitute within Octapharma's DMS and maintained within that donor's Donor History Record.

50. Next, the educational materials relating to the risks that a donor's behavior or infections pose to a Source Plasma recipient are read to the donor by the Medical Director or physician substitute and the donor is required to evidence their understanding by reciting 3 examples of risks cited in the educational materials.

51. The Medical Director or physician substitute then determines whether the donor has any allergies to materials used during the plasmapheresis procedure, including iodine, adhesives, latex and rubber.

52. Additional educational materials relating to HIV/AIDS are also reviewed by the Medical Director or physician substitute with the donor and after confirmation of the donor's review of the information, informed consent by the donor through electronic signature on the electronic signature pad device connected to the DMS, which consent is maintained in that donor's Donor History Record.

53. The final consent required of the donor is their acknowledgement of Octapharma's Informed Consent to Plasmapheresis, which informed consent is obtained from the donor at their initial visit prior to donation and annually thereafter.

54. The Medical Director or physician substitute presents and discusses all of the information contained in the form, which summarizes all information and consents previously discussed with the donor and currently requires acknowledgement and consent to the following:

a. The donor's understanding of the difference between blood and plasma;

b. The donor's understanding of the plasmapheresis procedure;

c. The donor's acknowledgement of the required frequency of plasma donations required for the donor's plasma to be acceptable for use;

d. The donor's understanding that the donor must meet all required criteria any time they want to donate plasma and must answer screening questions truthfully;

e. The donor's understanding that the donor will be screened and possibly deferred prior to any donation, including answering health and medical questions, having their vital signs checked, having their blood tested, and being examined;

f. The donor's acknowledgement that the plasma donation procedure has numerous identified risks;

g. The donor's acknowledgement that the donor will contact Octapharma if they have a concern about any of the factors that may affect their eligibility or suitability as a plasma donor;

h. The donor's understanding that the donor's information will be kept confidential to the extent allowed by law, but that absolute confidentiality cannot be guaranteed. The information will be kept in a secure electronic or hard copy format accessible to Octapharma's authorized staff, but any of their information may be disclosed to the FDA and other companies that use the collected plasma and testing result information may be disclosed to healthcare professionals treating an Octapharma employee after an exposure incident;

i. The donor's acknowledgement that as part of the donation process, the donor's blood/plasma will be tested for numerous viral and blood/plasma diseases and that a positive or unsuitable result will be conveyed to the donor by a Medical Director or physician substitute who will discuss the result with them and may refer them to their healthcare provider for further testing, that the testing result may also cause the donor to be deferred (either temporarily or permanently), named in the national list of deferred donors, and/or reported to the local health department and other plasma companies; and that the testing is not to be used by the donor as a means for diagnosing diseases like HIV/AIDS;

j. The donor's understanding of the plasmapheresis process and its possible side effects or adverse reactions, the testing that will be performed on the donor's plasma/blood, the prohibition from using plasma donation for disease diagnosis, the possibility of deferral due to unsuitable blood/plasma test results or screening assessment, the compensation for donating plasma, the opportunity to ask questions and obtain satisfactory answers has been provided, and the ability to withdraw consent and stop donating plasma at any time; and

k. The donor's final acknowledgement that by signing the consent, the donor confirms that all of their questions to Octapharma have been answered, that the donor agrees to donate plasma that will be used to make medicines, and that the donor consents to donate plasma at Octapharma.

Octapharma maintains the Informed Consent for Plasmapheresis forms.

55. The donor's informed consent is provided through electronic signature on the electronic signature pad device connected to the DMS in the presence of the Medical Director or physician substitute, which consent is maintained in that donor's Donor History Record.

56. If eligible to donate, the Medical Director or physician substitute issues the compensation card to the donor through the DMS and prepares for the transfer of the donor to the phlebotomy area for the plasma donation procedure, including the generation of labels required for identification of all tubes and containers needed for the donor's collected blood and Source Plasma (the "Bleed Labels").

57. In accordance with applicable law and regulations, Octapharma has implemented policies and procedures for its collection of plasma and blood samples for testing, as well as the plasmapheresis procedure itself referred to as Octapharma's Automated Plasmapheresis-Plasma Collection policy ("Plasmapheresis Policy").

58. For the plasma collection procedure, since August, 2019, Octapharma uses Haemonetics' NexSys PCS device that is a FDA-registered medical device which performs the plasmapheresis procedure (using sterile supplies, collection of the donor's blood from the donor's vein, separation of red blood cells and platelets from plasma, return of the red blood cells and platelets to the donor and retention of the remaining plasma for collection) that allows a bi-directional connection with the donor management system information contained in Octapharma's DMS. The prior plasma collection system used by Octapharma, Haemonetics' PCS2, was also a FDA-registered medical device and its data was entered into the DMS by Octapharma employees manually (collectively, the NexSys PCS and PCS2 are the "PCS").

59. In accordance with its Suitability Policy and Plasmapheresis Policy, after being physically transferred to the phlebotomy area of Octapharma's facility, the donor is again positively identified and verified by the phlebotomist into the PCS.

60. The Plasmapheresis Policy requires that the Bleed Labels are reviewed and affixed by the phlebotomist to all needed sample tubes and plasma collection containers, reflect the unit container number and other information, including collection and expiration date, product code and barcode identification, thus enabling the DMS to identify each sample tube or container of blood or plasma collected from the donor back to the donor and relate each to the eventual testing result.

61. Pursuant to its Plasmapheresis Policy, each step of the plasma collection process is documented in the PCS, and the actual collection volume and any collection exceptions that happened during the procedure are transferred into the DMS and added to the donor's Donor History Record.

62. All required blood and plasma samples are collected and tested by Octapharma's clinical laboratory or an approved contract laboratory that is also FDA-registered and CLIA certified, pursuant to its CLIA and Illinois Laboratory Act licensures, in accordance with scientifically proven methodologies and its Suitability and Plasmapheresis Policies, before the donor's initial collected plasma can be used (and at regular intervals thereafter), and include Viral Marker Tests (VMT), Nucleic Acid Test/Polymerase Chain Reaction (NAT/PCR) Tests, Atypical Antibody (ATYA) or Antibody Screening (ABS), Rapid Plasma Reagin (RPR) Tests, Serum Protein Electrophoresis (SPE), and Blood Typing from a plasma sample (generally, a "Lab Test" or collectively, "Lab Tests").

63. Octapharma's clinical laboratory tracks all blood and plasma samples and documents all results for the Lab Tests using the Laboratory Information Management System (LIMS) which the DMS applies to the information into the donor's Donor History Record.

64. Results of the RPR and SPE Lab Tests must be specifically reviewed by the Medical Director or physician substitute within fourteen (14) days after the sample was drawn, and abnormal results resolved only by Medical Director review of an acceptable result.

65. Through its DMS, and subject to its Suitability Policy, Octapharma can determine and document that a donation of Source Plasma by a donor is suitable upon reviewing its records, the National Donor Deferral Registry records, and the CDCS records to determine that the donor is not a deferred donor, that the interval since the donor's last donation is appropriate, and that the donor's medical history based upon the medical history interview and physical assessment in the first visit, and the health interview and physical screening exam at subsequent visits to validate that the donor is in good health and would not be adversely affected by the donation, that the donor is free of risk factors for transmissible infections, and that the result of tests of the donor's blood is negative or nonreactive.

66. A suitable plasma donation is placed into an additional quarantine hold of 45 days until the donor is determined eligible to donate, during which time a subsequent deferral of the donor would preclude distribution of any of the collected Source Plasma for manufacture.

67. In order to become an eligible donor for Source Plasma, the donor must have a record of two occasions of negative Lab Test results for "relevant transfusion-transmitted infections" within the prior 6 months. Therefore, Octapharma requests that donors return for their second donation within seven days of their initial donation visit so that the donor's eligibility can

be assured most expeditiously, and the suitable collected Source Plasma released from the quarantine hold.

68. Through Octapharma's data input and monitoring the status of a donor's Donor History Record information and tracking an unacceptable Lab Test result or deferral within the DMS, Octapharma can ensure that any suitable Source Plasma obtained from a donor for further manufacturing into injectable products is not released for use until the donor is determined to be eligible to donate.

69. Octapharma always notifies the donor of a deferral or ineligibility to donate Source Plasma based upon a positive or reactive result after testing and uses the DMS to document the donor's Donor History Record accordingly.

70. In those instances, Octapharma contacts the donor and requests that the donor return to its facility, and Octapharma's licensed Medical Director or physician substitute counsels the donor about the reason for the deferral as being based upon the test result. Octapharma also provides documentation, including copies of the test results, so that the donor can take the information to their physician or transmit it to their physician, subject to HIPAA.

71. Upon the determination from the DMS that a donor is eligible, Octapharma labels each container containing the Source Plasma collected from each individual donor for manufacture or distribution, and then labels each case containing the Source Plasma container, for distribution and use with required information that includes expiration date, lot number and bar code identification for each container.

72. Each Octapharma employee has a unique login to DMS. After login, all actions performed in the system are date/timestamped under that individual's login, and any changes to information are recorded in the DMS for traceability, thus as Octapharma prepares other records

concurrently with the performance of each step in the manufacture and distribution of Source Plasma, any time successive steps in the manufacture and distribution of any lot they can be traced by an inspector to ensure its records are legible and indelible, identify the person immediately responsible, include dates of the various steps, and are as detailed as necessary for clear understanding of each step by one experienced in the manufacture of products.

73. Octapharma maintains in each donor's Donor History Record through the DMS, data records that include a complete record of all information requested of and responded to by the donor and information inputted by Octapharma's employees, including the Medical Screener, Medical Director, physician substitute or phlebotomist, relating to obtaining Positive Donor Identification and to each and every 1) examination, 2) serologic or other test result, including for "relevant transfusion-transmitted infections," 3) sample tube and collection container label information, 4) laboratory data result, 5) interview or questionnaire, 6) informed consents obtained from the donor, including for the plasmapheresis procedure, and 7) records otherwise used to determine the eligibility of a donor for each donation or the suitability of each Source Plasma donation, and/or a full explanation for any suitability rejection, 8) records of any donor reaction while on the plasmapheresis premises or reported to the center after the donor has left the premises which includes a full explanation of the reaction, the measures taken to assist the donor, and the outcome of the incident. Within the DMS, the data comprising the Donor History Record of a donor created during a particular donation visit will cross-reference and relate with data comprising the Donor History Record created for each and every other donation visit by that donor at Octapharma.

74. Through the DMS, Octapharma also cross-references each donor's Donor History Record, which includes proof of Positive Donor Identification, ultimately to each unit(s) of manufactured Source Plasma associated with the donor from that donation visit.

75. Octapharma, through its DMS, retains its Donor History Records and its records relating to the donor's blood and plasma testing, and its manufacture of Source Plasma for the period no less than five years after manufacture has been completed, or six months after the latest expiration date for the individual product, whichever represents a later date, to permit the return of any clinical report of unfavorable reactions from a lot of Source Plasma.

76. Because all of the information was inputted by the donor or Octapharma's employees into the DMS, each inputted data point interconnects and relates to each requirement of its Screening Policy (and related procedures in its Screening Evaluation and Physical Examination), Plasmapheresis Policy, and/or Positive Donor Identification.

77. Further, by its DMS' maintenance of all the information relating to each donor's specific donation visit within one data management source, Octapharma complies with the regulatory requirement that the data be maintained for at least 5 years to allow Octapharma and/or regulators to investigate a donor's donation in the event of an unfavorable result traced to Source Plasma obtained from that donor on that specific date. Octapharma can access the underlying data for review and/or generate reports from the DMS that reflect each step of the processes specified in Octapharma's Screening Policy (and related procedures in its Screening Evaluation and Physical Examination), Plasmapheresis Policy, and Positive Donor Identification, during a donor's donation visit was properly conducted, evaluated and documented, evidencing compliance with all applicable federal regulations.

78. In accordance with applicable law and regulations, Octapharma also has developed an External Audit Policy that details the requirements and procedures to be followed in the event that Octapharma is contacted by regulators, registration bodies, or customers regarding its compliance with any applicable law or regulation.

79. The External Audit Policy reflects the requirements relating to any investigator or auditor's visit to Octapharma; as well as specific guidelines for document requests and review; staff interview requests; and specific limitations on information accessible to the FDA, OSHA and customers.

80. In accordance with its External Audit Policy, Octapharma must allow inspections and audits by FDA inspectors for purposes of obtaining and maintaining its Biologics license.

81. Given the private nature of its donors' information, Octapharma has developed an information security framework of policies and training materials, based on factors such as information ownership, categorization of potential impacts, systems inventory, data management, risk management, and third-party information risk management. The policies cover information security incident reporting and requirements for mandatory training of its employees and third parties authorized to access Octapharma's information systems.

[Signature Page to Follow]

Dated this 17th day of July, 2020.

Monica H Byrd

MONICA H. BYRD

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	**FEI:** 3006200209 **DUNS:** 033542827 **U.S. License Number:** 1817	**REASON FOR SUBMISSION** Annual Registration	**DISTRICT OFFICE:** Chicago **VALIDATED BY FDA:** 11/11/2019
LEGAL NAME AND LOCATION: Octapharma Plasma, Inc. 418 Hill Avenue Aurora, IL 60505 USA 630-375-0228	**REPORTING OFFICIAL:** Monica H. Byrd Octapharma Plasma, Inc. 10644 Westlake Drive Charlotte, NC 28273 USA 704-654-4600 us2regulatoryalerts@octapharmaplasma.com		**U.S. AGENT:**
OTHER NAMES USED IN THIS LOCATION:	**TYPE OF OWNERSHIP:** CORPORATION **DONOR/RECIPIENT RELATIONSHIP:**		**ESTABLISHMENT TYPE:** PLASMAPHERESIS CENTER

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
SOURCE PLASMA			X						X			

***** End Of Report *****

EXHIBIT 1
to Declaration of
Monica H. Byrd

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	**FEI:** 3015224706 **DUNS:** 116967362 **U.S. License Number:** 1817	**REASON FOR SUBMISSION** Annual Registration	**DISTRICT OFFICE:** Chicago **VALIDATED BY FDA**: 05/04/2020
LEGAL NAME AND LOCATION: Octapharma Plasma, Inc. 8735 S. Harlem Avenue Bridgeview, IL 60455 USA 708 572-7107	**REPORTING OFFICIAL:** Monica H. Byrd Octapharma Plasma, Inc. 10644 Westlake Dr Charlotte, NC 28273 USA 704-654-4600 us2regulatoryalerts@octapharmaplasma.com		**U.S. AGENT:**
OTHER NAMES USED IN THIS LOCATION:	**TYPE OF OWNERSHIP:** CORPORATION **DONOR/RECIPIENT RELATIONSHIP:**		**ESTABLISHMENT TYPE:** PLASMAPHERESIS CENTER

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
SOURCE PLASMA			X						X			

***** End Of Report *****

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	**FEI:** 3013154109 **DUNS:** 066838598 **U.S. License Number:** 1817	**REASON FOR SUBMISSION** Annual Registration	**DISTRICT OFFICE:** Chicago **VALIDATED BY FDA:** 11/11/2019
LEGAL NAME AND LOCATION: Octapharma Plasma, Inc. 16845 Torrence Ave. Lansing, IL 60438 USA 708 418-5258	**REPORTING OFFICIAL:** Monica H. Byrd Octapharma Plasma, Inc. 10644 Westlake Drive Charlotte, NC 28273 USA 704 654-4600 us2regulatoryalerts@octapharmaplasma.com		**U.S. AGENT:**
OTHER NAMES USED IN THIS LOCATION:	**TYPE OF OWNERSHIP:** CORPORATION **DONOR/RECIPIENT RELATIONSHIP:**		**ESTABLISHMENT TYPE:** PLASMAPHERESIS CENTER

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
SOURCE PLASMA			X						X			

***** End Of Report *****

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	**FEI:** 3007426399 **DUNS:** 034618387 **U.S. License Number:** 1817	**REASON FOR SUBMISSION** Annual Registration	**DISTRICT OFFICE:** Chicago **VALIDATED BY FDA:** 11/11/2019
LEGAL NAME AND LOCATION: Octapharma Plasma, Inc. 3644 Avenue of the Cities Moline, IL 61265 USA 309-757-9030	**REPORTING OFFICIAL:** Monica H. Byrd Octapharma Plasma, Inc. 10644 Westlake Drive Charlotte, NC 28273 USA 704-654-4600 us2regulatoryalerts@octapharmaplasma.com		**U.S. AGENT:**
OTHER NAMES USED IN THIS LOCATION:	**TYPE OF OWNERSHIP:** CORPORATION **DONOR/RECIPIENT RELATIONSHIP:**		**ESTABLISHMENT TYPE:** PLASMAPHERESIS CENTER

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
SOURCE PLASMA			X						X			

***** End Of Report *****

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	**FEI:** 3015224725 **DUNS:** 116967927 **U.S. License Number:** 1817	**REASON FOR SUBMISSION** Annual Registration	**DISTRICT OFFICE:** Chicago **VALIDATED BY FDA:** 03/17/2020
LEGAL NAME AND LOCATION: Octapharma Plasma, Inc. 7379 West 25th Street North Riverside, IL 60546 USA 708 221-9986	**REPORTING OFFICIAL:** Monica H. Byrd Octapharma Plasma, Inc. 10644 Westlake Drive Charlotte, NC 28273 USA 704 654-4600 us2regulatoryalerts@octapharmaplasma.com		**U.S. AGENT:**
OTHER NAMES USED IN THIS LOCATION:	**TYPE OF OWNERSHIP:** CORPORATION **DONOR/RECIPIENT RELATIONSHIP:**		**ESTABLISHMENT TYPE:** PLASMAPHERESIS CENTER

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
SOURCE PLASMA			X						X			

***** End Of Report *****

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	**FEI:** 3011195529 **DUNS:** 027452446 **U.S. License Number:** 1817	**REASON FOR SUBMISSION** Annual Registration	**DISTRICT OFFICE:** Chicago **VALIDATED BY FDA:** 11/11/2019
LEGAL NAME AND LOCATION: Octapharma Plasma, Inc. 17 West North Ave. Northlake, IL 60164 USA 708-409-0900	**REPORTING OFFICIAL:** Monica H. Byrd Octapharma Plasma, Inc. 10644 Westlake Drive Charlotte, NC 28273 USA 704-654-4600 us2regulatoryalerts@octapharmaplasma.com		**U.S. AGENT:**
OTHER NAMES USED IN THIS LOCATION:	**TYPE OF OWNERSHIP:** CORPORATION **DONOR/RECIPIENT RELATIONSHIP:**		**ESTABLISHMENT TYPE:** PLASMAPHERESIS CENTER

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
SOURCE PLASMA			X						X			

***** End Of Report *****

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	**FEI:** 3006188513 **DUNS:** 004640158 **U.S. License Number:** 1817	**REASON FOR SUBMISSION** Annual Registration	**DISTRICT OFFICE:** Chicago **VALIDATED BY FDA:** 11/11/2019
LEGAL NAME AND LOCATION: Octapharma Plasma, Inc. 1770 Wabash Avenue Springfield, IL 62704 USA 217-546-8605	**REPORTING OFFICIAL:** Monica H. Byrd Octapharma Plasma, Inc. 10644 Westlake Drive Charlotte, NC 28273 USA 704-654-4600 us2regulatoryalerts@octapharmaplasma.com		**U.S. AGENT:**
OTHER NAMES USED IN THIS LOCATION:	**TYPE OF OWNERSHIP:** CORPORATION **DONOR/RECIPIENT RELATIONSHIP:** ALLOGENIC		**ESTABLISHMENT TYPE:** COLLECTION FACILITY; PLASMAPHERESIS CENTER

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X											
SOURCE PLASMA			X						X			
BLOOD PRODUCTS FOR DIAGNOSTIC USE	X			X					X			

***** End Of Report *****

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

OCTAPHARMA PLASMA INC
418 HILL AVE
AURORA, IL 60505

CLIA ID NUMBER

14D1004873

EFFECTIVE DATE

02/18/2014

LABORATORY DIRECTOR

BARBARA R BELLAR M D

EXPIRATION DATE

02/17/2016

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

209 Certs2_012114

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	02/18/2010		

EXHIBIT 2
to Declaration of
Monica H. Byrd

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CLIA ID Number: 14D1004873
OCTAPHARMA PLASMA INC
418 HILL AVE
AURORA, IL 60505

STATE AGENCY ADDRESS AND PHONE NUMBER:

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
DIV OF HEALTH CARE FACILITIES & PROGRAMS
525 W JEFFERSON ST/FOURTH FLR
SPRINGFIELD, IL 62761
(217)782-6747

LABORATORY MAILING ADDRESS:

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

OCTAPHARMA PLASMA INC
418 HILL AVE
AURORA, IL 60505

CLIA ID NUMBER

14D1004873

EFFECTIVE DATE

02/18/2016

LABORATORY DIRECTOR

BARBARA R BELLAR M D

EXPIRATION DATE

02/17/2018

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

75 Certs2_011916

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	02/18/2010		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
418 HILL AVE
AURORA, IL 60505

CLIA ID NUMBER
14D1004873

EFFECTIVE DATE
02/18/2018

LABORATORY DIRECTOR
BARBARA R BELLAR M D

EXPIRATION DATE
02/17/2020

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

76 Certs2_012318

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	02/18/2010		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF REGISTRATION

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA, INC
8735 S HARLEM AVE
BRIDGEVIEW, IL 60455

CLIA ID NUMBER
14D2157670

EFFECTIVE DATE
11/09/2018

LABORATORY DIRECTOR
THANH LAN M D

EXPIRATION DATE
11/08/2020

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

249 Certs1_112718

- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA, INC
8735 S HARLEM AVE
BRIDGEVIEW, IL 60455

CLIA ID NUMBER
14D2157670

EFFECTIVE DATE
05/13/2019

LABORATORY DIRECTOR
MARIANNE GREENE M D

EXPIRATION DATE
05/12/2021

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

88 Certs2_062519

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	05/13/2019		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

OCTAPHARMA_000331

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA, INC
4760 S KEDZIE AVE
CHICAGO, IL 60632

CLIA ID NUMBER
14D2172782

EFFECTIVE DATE
01/17/2020

LABORATORY DIRECTOR
KENNETH P WIND

EXPIRATION DATE
01/16/2022

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

94 certs2_022520

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	01/17/2020		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF REGISTRATION

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
16845 TORRENCE AVE
LANSING, IL 60438

CLIA ID NUMBER
14D2120214

EFFECTIVE DATE
10/12/2016

LABORATORY DIRECTOR
STEPHEN BLATT MD

EXPIRATION DATE
10/11/2018

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.
This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

346 Certs1_110116

- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
16845 TORRENCE AVE
LANSING, IL 60438

CLIA ID NUMBER
14D2120214

EFFECTIVE DATE
03/30/2019

LABORATORY DIRECTOR
BARBARA BELLAR M D

EXPIRATION DATE
03/29/2021

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

120 Certs2_030519

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	03/30/2017		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
16845 TORRENCE AVE
LANSING, IL 60438

CLIA ID NUMBER
14D2120214

EFFECTIVE DATE
03/30/2019

LABORATORY DIRECTOR
RUPAL PARMAR M D

EXPIRATION DATE
03/29/2021

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

72 certs2_111919

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	03/30/2017		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

OCTAPHARMA PLASMA INC
3644 AVENUE OF THE CITIES
MOLINE, IL 61265

CLIA ID NUMBER
14D1094977

EFFECTIVE DATE
10/22/2012

LABORATORY DIRECTOR
DENNIS D PALMER D O

EXPIRATION DATE
10/21/2014

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

237 Certs2_092212

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	10/22/2010		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

OCTAPHARMA PLASMA INC
3644 AVENUE OF THE CITIES
MOLINE, IL 61265

CLIA ID NUMBER

14D1094977

EFFECTIVE DATE

10/22/2014

LABORATORY DIRECTOR

DENNIS D PALMER D O

EXPIRATION DATE

10/21/2016

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

103 Certs2_092314

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	10/22/2010		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CLIA ID Number: 14D1094977
OCTAPHARMA PLASMA INC
ATTN REGULATORY AFFAIRS
3525 WHITEHALL PARK DR, STE 500
CHARLOTTE, NC 28273

STATE AGENCY ADDRESS AND PHONE NUMBER:

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
DIV OF HEALTH CARE FACILITIES & PROGRAMS
525 W JEFFERSON ST/FOURTH FLR
SPRINGFIELD, IL 62761
(217)782-6747

LABORATORY MAILING ADDRESS:

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
3644 AVENUE OF THE CITIES
MOLINE, IL 61265

CLIA ID NUMBER
14D1094977

EFFECTIVE DATE
10/22/2016

LABORATORY DIRECTOR
WILLIAM RANKIN MD

EXPIRATION DATE
10/21/2018

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

89 Certs2_092716

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	10/22/2010		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
3644 AVENUE OF THE CITIES
MOLINE, IL 61265

CLIA ID NUMBER
14D1094977

EFFECTIVE DATE
10/22/2018

LABORATORY DIRECTOR
WILLIAM RANKIN MD

EXPIRATION DATE
10/21/2020

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

95 certs2_092518

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	10/22/2010		

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CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA, INC
7379 W 25TH ST
NORTH RIVERSIDE, IL 60546

CLIA ID NUMBER
14D2158499

EFFECTIVE DATE
05/16/2019

LABORATORY DIRECTOR
KENNETH WIND

EXPIRATION DATE
05/15/2021

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

74 Certs2_041420

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	05/16/2019		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
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CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF REGISTRATION

LABORATORY NAME AND ADDRESS

OCTAPHARMA PLASMA INC
17 WEST NORTH AVE
NORTHLAKE, IL 60164

CLIA ID NUMBER

14D2083467

EFFECTIVE DATE

09/05/2014

LABORATORY DIRECTOR

MOON-WOO NAM MD

EXPIRATION DATE

09/04/2016

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

495 Certs1_092314

- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CLIA ID Number: 14D2083467
OCTAPHARMA PLASMA INC
ATTN REGULATORY AFFAIRS
3525 WHITEHALL PARK DR, STE 500
CHARLOTTE, NC 28273

STATE AGENCY ADDRESS AND PHONE NUMBER:

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
DIV OF HEALTH CARE FACILITIES & PROGRAMS
525 W JEFFERSON ST/FOURTH FLR
SPRINGFIELD, IL 62761
(217)782-6747

LABORATORY MAILING ADDRESS:

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

OCTAPHARMA PLASMA INC
17 WEST NORTH AVE
NORTHLAKE, IL 60164

CLIA ID NUMBER

14D2083467

EFFECTIVE DATE

06/30/2015

LABORATORY DIRECTOR

STEPHEN ANDREW BLATT MD

EXPIRATION DATE

06/29/2017

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

94 Certs2_072815

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	06/30/2015		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
17 WEST NORTH AVE
NORTHLAKE, IL 60164

CLIA ID NUMBER
14D2083467

EFFECTIVE DATE
06/30/2017

LABORATORY DIRECTOR
STEPHEN ANDREW BLATT MD

EXPIRATION DATE
06/29/2019

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

81 Certs2_053017

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	06/30/2015		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
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CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
17 WEST NORTH AVE
NORTHLAKE, IL 60164

CLIA ID NUMBER
14D2083467

EFFECTIVE DATE
06/30/2017

LABORATORY DIRECTOR
TIMOTHY SUTTON MD

EXPIRATION DATE
06/29/2019

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

57 Certs2_120517

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	06/30/2015		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
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CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
17 WEST NORTH AVE
NORTHLAKE, IL 60164

CLIA ID NUMBER
14D2083467

EFFECTIVE DATE
06/30/2019

LABORATORY DIRECTOR
MARIANNE GREENE M D

EXPIRATION DATE
06/29/2021

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

61 certs2_060419

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	06/30/2015		

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CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS	CLIA ID NUMBER
OCTAPHARMA PLASMA INC 1770 WABASH AVE SPRINGFIELD, IL 62704	14D1052570
	EFFECTIVE DATE 07/12/2014
LABORATORY DIRECTOR	EXPIRATION DATE
KRISTEN FERGUSON MD	07/11/2016

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

93 Certs2_061714

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ROUTINE CHEMISTRY (310)	07/12/2010		

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CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
1770 WABASH AVE
SPRINGFIELD, IL 62704

CLIA ID NUMBER
14D1052570

EFFECTIVE DATE
07/12/2016

LABORATORY DIRECTOR
KRISTEN FERGUSON MD

EXPIRATION DATE
07/11/2018

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Survey and Certification Group
Center for Clinical Standards and Quality

72 Certs2_061416

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ROUTINE CHEMISTRY (310)	07/12/2010		

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CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
OCTAPHARMA PLASMA INC
1770 WABASH AVE
SPRINGFIELD, IL 62704

CLIA ID NUMBER
14D1052570

EFFECTIVE DATE
07/12/2018

LABORATORY DIRECTOR
KRISTEN FERGUSON MD

EXPIRATION DATE
07/11/2020

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Survey and Certification Group
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77 Certs2_061218

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ROUTINE CHEMISTRY (310)	07/12/2010		

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